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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,616

06/10/2005

Ilan Ziv

26549U

7134

20529

7590

02/21/2007

NATH & ASSOCIATES

112 South West Street

Alexandria, VA 22314

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/516,616

Applicant(s)

ZIV ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 84-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84,96,97,99-103,108 and 109 is/are rejected.
- 7) ☒ Claim(s) 85-95,98 and 104-107 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/3/04 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 12/3/04 wherein claims 1-83 were canceled; claims 84-89 were added; and the specification was amended.

Note: Claims 84-109 are pending.

APPLICANT'S INVENTION

2. The instant invention is directed to compounds of Formula II as set forth in independent claim 84 and uses thereof.

112 FIRST PARAGRAPH REJECTIONS

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 100-103 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue

Art Unit: 1618

experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The instant invention is directed to compounds as set forth in independent claim 84 and uses thereof. Review of the specification appears to indicate that due to some mode of action, specific conjugate combination may result in the treatment of tumors/cancers and possibly other 'diseases' such as infectious diseases.

(2) State of the prior art

The state of the prior art is that physiological disorders, for example, cancer, remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, October 15, 1999, pp. 531-537) that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types in order to maximize efficacy and minimize toxicity. The classification of cancer has been based primarily on morphological appearance of the tumor and that of tumors with similar histopathological appearance may follow significantly different clinical courses and have different responses to therapy (see Golub et al., Science, October 15, 1999, pp. 531-537). As a result, there is no absolute

Art Unit: 1618

predictability of which tumors are treatable/detectable at all times, even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the knowledge in the art would hinder one of ordinary skill in the art from accepting any therapeutic regimen as being acceptable for all tumor/cancer treatments or stating that at all times, cancerous cells are detectable. Thus, there is a vast range of infectious diseases that may occur based on the various biochemical pathways.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of the patients who have the potential of becoming afflicted with the numerous physiological disorders that are encompassed by the instant invention. The assumption that all physiological disorders may be detected using the instating invention is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for all physiological disorders, for example cancers.

(4) Level of predictability in the art

The art pertaining to the detection of physiological disorders is highly unpredictable since there exists a multitude of possible physiological disorders. Determining the various types or classes of disorders useful with the instant invention requires various experimental procedures and without guidance that is applicable to all disorders, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided

There is no evidence of record which would enable the skilled artisan in the identification of all physiological disorders claimed herein. Applicant's limited guidance does not enable the public to use the instant invention for such a number of disorders encompassed by the claim. There is no directional guidance for the types or classes of physiological disorders detectable with the instant invention. The evidence of record does not provide exactly what physiological disorders Applicant is referring to. Hence, there is no enablement for all possible physiological disorders detectable with the claimed invention.

(6) Existence of working examples

Independent claim 100 encompasses a vast number of physiological disorders. Applicant's limited working examples do not enable the public to use such detection methods for a vast number of disorders.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible physiological disorders known to exist. . For example, there are many classes of disorders such as allogeneic, communicable, congenital, contagious, deficiency, endemic, functional, hereditary, infectious, local, occupational, organic, periodic, social, systemic, and so forth that are known to affect a subject.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the

Art Unit: 1618

specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 84, 96, 97, 99, 100, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84: The claim as written is ambiguous because Applicant has not defined the variable R. However, the claim was examined with the R values disclosed on page 5, lines 5-7, of the specification.

Claim 84, lines 17-20: The claim contains improper Markush language (Applicant's attention is directed to MPEP 803.02). In particular, the term 'comprising' is not acceptable Markush terminology.

Claim 84, line 19-20: The claim as written is ambiguous because it is unclear what label(s) Applicant is/are claiming to be compatible with the instant invention. In particular, it is unclear what is intended by the phrase 'a label capable of undergoing an enzymatic reaction that produces a detectable color'.

Claim 96, lines 1-2: The claim as written is ambiguous because of the phrase 'said metal being comprised within the Q moiety of the compound of claim 84'. It is respectfully suggested that Applicant delete the phrase 'said metal being comprised within the Q moiety of the compound of claim 84' because review of claim 84 indicates that the only location for attachment of a metal is with the Q moiety.

Claim 97: The claim as written is ambiguous because it is unclear what Applicant what properties Applicant is referring to that are compatible with the active compound.

Claim 99, lines 4-5: The claim as written is ambiguous because of the phrase 'significant amount'. In particular, the phrase varies from person to person. Thus, one person may consider 58% to be significant while another may consider 90% to be a significant amount. Please clarify in order that one may readily determine what is being claimed.

Claims 100 and 109: Independent claim 100 as written is ambiguous because it is unclear what specific physiological disorders are being claimed.

Claim 108, line 2: The claim is ambiguous because it is unclear how one monitors aggressiveness of a tumor based on the steps disclosed in claim 96.

CLAIM OBJECTIONS

7. Claims 85-95, 98, and 104-107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

PRIORITY DOCUMENT

8. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

COMMENTS/NOTES


9. It should be noted that no prior art has been cited against the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compounds of formula II as set forth in independent claim 84 and uses thereof.

10. Applicant is respectfully requested to replace 'including' with 'and' in claim 84, line 4. In addition, Applicant is respectfully requested to make the following changes in order to clarify the instant invention: (1) claim 85, line 4, replace both occurrences of 'among' with 'from the group consisting of'; (2) claim 85, line 5, replace 'including' with 'and'; (3) claims 86-88, 91, 92, 93, and 94, line 4, replace 'including' with 'and'; (4) claim 89, line 6, replace 'including' with 'and'; (5) claim 90, line 5, replace 'including' with 'and'; (6) claim 95, line 1, replace 'among' with 'from the group consisting of'; (7) claim 98, line 2, after 'is' insert 'selected from the group consisting of'; (8) claim 99, last line, delete the extra '.' (period); and (9) claims 105 and 107, line 2, replace 'among' with 'from'.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

February 2, 2007